



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

|   |             |                      |                         |                  |
|---|-------------|----------------------|-------------------------|------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
| 09/897,898  | 07/05/2001  | Harm M. Deckers      | 034547-0104             | 3117             |
| 22428 7590 12/18/2006<br>FOLEY AND LARDNER LLP<br>SUITE 500<br>3000 K STREET NW<br>WASHINGTON, DC 20007 |             |                      | EXAMINER<br>PAK, YONG D |                  |
|   |             |                      | ART UNIT                | PAPER NUMBER     |
|   |             |                      | 1652                    |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE           |                  |
| 3 MONTHS  |             | 12/18/2006           | PAPER                   |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/897,898

Applicant(s)

DECKERS ET AL.

Examiner

Yong D. Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14,15,18 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-15, 18 and 29-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This application is a CIP of 09/577,147, now issued as U.S. Patent No. 6,372,234.

The amendment filed on September 26, 2006, amending claims 14-15, 18 and 29, canceling claims 16-17 and adding claims 30-31, has been entered.

Claims 14-15, 18 and 29-31 are pending and are under consideration.

### ***Response to Arguments***

Applicant's amendment and arguments filed on September 26, 2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-15, 18 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moloney et al., Wieles et al., Rooijen et al. and Murphy et al.

Claims 14-15, 18 and 29-31 are drawn to a method of making an emulsion by transforming a plant cell, such as a rapeseed cell, with a chimeric polynucleotide comprising a polynucleotide that regulates transcription in a cell linked to a polynucleotide encoding a fusion protein comprising at least the central domain of an oleosin and a thioredoxin or thioredoxin reductase which is further linked to a polynucleotide that terminates transcription in the plant cell, wherein oil bodies comprising the fusion protein is isolated and washed such that substantially intact oil bodies are obtained, which is then formulated into an emulsion. Claim 29 limits claim 14 in that the thioredoxin or thioredoxin reductase of the emulsion reduces a target.

Moloney et al. (WO 96/21029 - form PTO-1449) discloses method of producing a fusion protein by introducing into a plant cell (page 26), a chimeric polynucleotide comprising a polynucleotide that regulates transcription in a cell linked to a polynucleotide encoding a fusion protein comprising a portion of an oleosin obtained from plant and a heterologous protein of interest which is further linked to a polynucleotide capable of terminating transcription in a plant cell, (pages 2-3). The method of Moloney et al. comprises growing said transformed plant host cell under

conditions permitting expression of said fusion polypeptide, isolating oil bodies comprising said fusion polypeptide and washing said oil bodies comprised of intact oil bodies via centrifugation (pages 2-3 and 10-11). Centrifugation is given as an example of "washing oil bodies", page 12. Also, since Moloney et al. also teaches that the enzyme of the fusion protein retains its enzymatic properties (page 21) indicating the heterologous protein is intact, Examiner takes the position that the "washed oil body preparation" comprising the fusion protein of Moloney et al. is "substantially intact".

The difference between the reference of et al. and the instant invention is that the reference of Moloney et al. does not teach a method of emulsifying the washed oil bodies comprising the fusion protein, wherein the heterologous protein is a thioredoxin or a thioredoxin reductase and the "portion of an oleosin" is the central domain of an oleosin and wherein the fusion protein is produced in a rapeseed cell.

Polynucleotides encoding many thioredoxin and thioredoxin reductases are known in the art see NiceZyme: EC 1.8.1.9 – cited previously on form PTO-892). Wieles et al. (cited previously on form PTO-892) discloses a polynucleotide encoding a thioredoxin and thioredoxin reductase and production of thioredoxin and thioredoxin reductase expressed in bacteria (abstract and pages 921-922). Wieles et al. also discloses that thioredoxin and thioredoxin reductase are involved in redox regulation and catalytic mechanism (abstract and page 921). Wielses et al. does not disclose expression and production of thioredoxin and thioredoxin reductase in plant cells or rapeseed cells.

Rooijen et al. (Biotechnology (N Y). 1995 Jan;13(1):72-7 - form PTO-1449) discloses a method of production and isolation of heterologous proteins in plant cells, such as rapeseed cells, by fusing a oleosin to the heterologous protein, wherein the oleosin facilitates separation of the heterologous protein from other cellular proteins (page 72 and abstract). Rooijen et al. discloses that said oleosin- heterologous protein fusion protein is enzymatically active and resides on the oil bodies and may be used directly in heterogeneous catalysis (abstract and Figure 5 on page 76). Rooijen et al. also discloses that after a round of catalysis the fusion protein may be recovered and reused several times without loss of activity and that production of these fusion proteins is extremely inexpensive, offering a novel route to the manufacture of recombinant proteins (abstract). Rooijen et al. also discloses that oil-bodies remain intact after aqueous extraction (or washing) (page 72). With the teachings of Rooijen et al. at hand, one having ordinary skill in the art would have recognized the advantage of producing thioredoxin and thioredoxin reductase using the method of Moloney et al. as opposed to its production in bacterial cells.

Murphy et al. (INFORM. Vol. 4. no. 8 (August 1993) – form PTO-1449) discloses that oleosins have a central hydrophobic domain (page 925, central column), which permits the oleosin to be embedded in oil bodies. With this teaching at hand, one having ordinary skill in the art would have recognized to use an oleosin comprising its central hydrophobic domain or full length oleosin. Murphy et al. also discloses that oleosins act as emulsifying agents and/or as emulsion-stabilizing agents (page 931).

Therefore, combining the teachings of Moloney et al., Wieles et al., Rooijen et al. and Murphy et al., it would have been obvious to one having ordinary skill in the art to modify the method of Moloney et al. by making a chimeric construct comprising a fusion protein wherein the heterologous protein is the thioredoxin or thioredoxin reductase of Wieles et al. and the portion of an oleosin is a central domain of an oleosin, express the chimeric construct in a rapeseed cell and to formulate the fusion protein into an emulsion. One of ordinary skill in the art would have been motivated to use thioredoxin or thioredoxin reductase as the heterologous protein in the fusion protein of Moloney et al. in order to inexpensively produce thioredoxin and thioredoxin reductase in plant cells, wherein the fusion protein can be re-used several times in catalysis. One of ordinary skill in the art would have been motivated to use oleosins comprising its central domain because Murphy et al. teaches that the central domain of oleosins are hydrophobic, which allows the oleosin to be embedded into the oil body. One of ordinary skill in the art would have been motivated to formulate the fusion protein into an emulsion to increase stability of the fusion protein for its re-use in catalysis. One of ordinary skill in the art would have had a reasonable expectation of success of making a fusion protein and isolating the fusion protein since Moloney et al. disclose a method of making a polynucleotide encoding a fusion proteins comprising oleosins and heterologous protein and Rooijen et al. discloses production of said fusion protein in a rapeseed cell and isolation of the fusion protein. One of ordinary skill in the art would have had a reasonable expectation of success in making an emulsion comprising said fusion protein since Murphy et al. teaches that oleosins are emulsifying agents.

Therefore, the above references render claims 14-15, 18 and 29-31 *prima facie* obvious to one of ordinary skill in the art.

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax



Application/Control Number:  
09/897,898  
Art Unit: 1652

Page 8

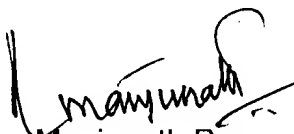
phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).



Yong D. Pak  
Patent Examiner 1652



Manjunath Rao  
Primary Patent Examiner 1652